

REMARKS

This application has been amended in a manner that is believed to place it condition for allowance at the time of the next Official Action.

Claims 1-17 are pending in the present application. Support for new claims 14-17 may be found in the original claims and generally throughout the specification. In particular, support for new claims 14-17 may be found at pg. 2, lines 20-30.

Applicant believes that the proposed combination of KOLTER et al. in view of CALOIANU et al. and END et al. fails to disclose or suggest the claimed invention.

KOLTER et al. is directed to the stable aqueous solubilizates of carotenoids and vitamins which are prepared with the aid of non-ionic emulsifiers.

END et al. teach a process for the preparation of beta-carotene together with an emulsifier by briefly heating the beta-carotene together with an emulsifier to give a homogenous solution.

CALOIANU et al. disclose a nutrient of a cosmetic cream product. The outstanding Official Action alleges that CALOIANU et al. teach the use of 2-5% isopropyl myristate and 0.01 to 0.1% of vitamin E in a 0.01 to 0.05% beta-carotene containing composition.

In imposing the rejection, applicants believe that the Examiner uses an improper analysis for determining a *prima facie* case of obviousness. The Examiner is respectfully reminded that to establish a *prima facie* case of obviousness, three basic criteria must be met.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference. Second, there must be a reasonable expectation of success. Third, the reference must teach or suggest all the claim recitations.

The teaching or suggestion to make the claimed invention and the reasonable expectation of success must be found in the reference, and not based on applicant's disclosure. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP §2143-2143.03. Upon reviewing the outstanding Official Action, it is believed that the Official Action fails to satisfy these criteria.

Applicant believes that one of ordinary skill in the art would lack the motivation and reasonable expectation of success of combining and modifying the cited publications to obtain the claimed invention.

Applicant believes that one of ordinary skill in the art would lack the motivation to combine the teachings of a

cosmetic cream composition disclosed by CALOIANU et al. with the stable solutions disclosed by KOLTER et al. and END et al.

While the outstanding Official Action alleges that the skilled artisan would have known that isopropyl myristate can be employed in beta-carotene injection formations as a solvent and cites to several publications in support of this contention, the outstanding Official Action fails to identify where the motivation and a reasonable expectation of success would be for one skilled in the art to actually combine and modify the teachings of these cited publications to obtain the claimed invention. As a result, applicant believes that the outstanding Official Action has failed to meet its burden in showing that the cited publications render obvious the claimed invention.

Indeed, applicant believes that KOLTER et al. teach away from the claimed invention. The Examiner's attention is respectfully directed to Example 7. KOLTER et al. is not able to produce a stable formulation of beta-carotene with only using Solutol HS15 and water, or by using Solutol HS 15 in a small quantity of tocopheral (1.2%) without using additional ascorbic acid.

This stands in contrast to the present invention wherein the claimed process enables the production of a clear and stable solution by using 0.1 to 10% (w/v) beta-carotene, 10-40%

(w/v) polyoxydrhylene-660-hydroxy-stearate and 5-20% (w/v) isopropyl myristate.

At this time, the Examiner's attention is respectfully directed to new claims 14-17. New claims 14-17 also recite a method for preparing a formulation of bet-carotene in an aqueous medium. Claim 14 recites that ascorbyl palmitate and/or alpha-tocopherol may be the antioxidants. Claim 16 recites that ascorbyl palmitate is present but that alpha-tocopherol is not present. As KOLTER et al. teach that tocopherol is an important part of their invention (col. 2, line 65 to col. 3, line 2). Applicants believe that the teachings of Kolter et al. teach away from the claimed invention. Indeed, all of the examples utilized by Kolter et al., rely on tocopherols.

As a result, it is believed that the proposed combination of KOLTER et al., END et al. and CALOIANU et al. fail to disclose or suggest the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 1-17, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

Application No. 10/085,000
Amdt. Dated May 7, 2004
Reply to Office Action of May 7, 2003
Docket No. 4301-1005-1

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

An RCE is being filed concurrently with this amendment.

Respectfully submitted,

YOUNG & THOMPSON

Philip A. DuBois
Philip A. DuBois, Reg. No. 50,696
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

PD/mjr

May 7, 2004